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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,383

06/27/2005

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EXAMINER

FRITCHMAN, REBECCA M

ART UNIT

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1797

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,383	<b>Applicant(s)</b> LARSEN ET AL.	
	<b>Examiner</b> REBECCA FRITCHMAN	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Detailed Action  
Summary***

This is the FINAL Office action based on the 10517383 application attorney remarks filed 02/18/2009.

Claims 22-48 are pending and have been fully considered.

***Claim Rejections - 35 USC § 103***

1. **Claims 22-48 are rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of MALLINCKRODT in EP 1182457(as cited on IDS dated 02/16/2005).**

With respect to Claim 22, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation(column 3, lines 28-31, column 4, lines 13-14), comprising a housing with characterizing particles suspended in a liquid sample(liquid storage chamber)(column 3, lines 28-31, column 3, lines 39-48), connectors for operational connection to and disconnection from connectors of a docking station for establishment of an electrical and fluid connections when the cartridge is received in the docking station(column 4, lines 4-15, column 6, lines 7-22), a first mixing chamber(column 4, lines 57-61), a first cell characterization means for characterizing cells passing through the first orifice(column 4, lines 4-15), a bore in the outer surface of the housing for the entrance of the blood sample(column 4, lines 24-33,

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“channel 54”), communicating with a first sampling member positioned in the housing for sampling the bloods sample and having a first cavity for receiving and holding the blood sample(column 3, lines 49-55, figures 2-4; first cavity: “through channel 53”), the member being movably positioned in relation to the housing in such a way that the first cavity is in communication with the bore for entrance of the blood into the first cavity(column 3, lines 56-62), and, in second position, the first liquid storage chamber(“intake channel 54”, column 3, lines 56-62, column 4, lines 28-33) communicates through the first cavity with the first mixing member so that the blood sample can be flushed with discharged liquid from the first liquid storage chamber into the first mixing chamber(column 3, lines 63-67, column 4, lines 55-65), characterized in that the cartridge further comprises a first collection chamber separated by a wall from the first mixing chamber, the wall containing a first orifice for the passage of the particles between the first mixing chamber and the first collection chamber(column 5, lines 18-24), and in that the first particle characterization means is adapted for characterization of the particles passing through the first orifice(column 5, lines 18-30). BERNDTSSON does not teach of the first liquid storage chamber holding a lysing reagent with a lysing capability sufficient for lysing erythrocytes while maintaining the counting ability of other blood cell types. MALLINCKRODT, however teaches of the use of such a reagent (Page 11, Table 1) in a cell counter in which the reagent is held within the cell counter(paragraph 0011-0013). It would have been obvious to use the lysing reagent of MALLINCKRODT in one of the liquid reagent containers of BERNDTSSON if one wanted to count only white blood cells due to known problems and the need in the

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art for an aperture device in which different types of cells can be counted directly (MALLINCKRODT, paragraphs 0006 & 0007).

With respect to Claim 23, MALLINCKRODT teaches of the lysing reagent containing a surfactant (sodiumdodecylsulfate) (Page 11, Table 1).

With respect to Claim 24, MALLINCKRODT teaches of the lysing reagent containing a surfactant (sodiumdodecylsulfate) (Page 11, Table 1). MALLINCKRODT does not teach of the use of saponin, however, saponin is an equivalent chemical for its use in the lysing agent as a surfactant.

With respect to Claim 25, MALLINCKRODT teaches of lysing reagent containing a quaternary ammonium salt (Page 11, Table 1).

With respect to Claims 26-28, MALLINCKRODT teaches of the use of isotonic solutions to be used with the lysing agent to minimize debris from red blood cells (paragraph 0022, and page 11, table 1).

With respect to Claim 29, MALLINKRODT teaches of the use of a urea compound in the diluent to be mixed with the lysing reagent (Claim 10).

With respect to Claim 30, MALLINKRODT teaches of the use of cyanide for converting the product to a product suitable for spectrophotometric analysis (paragraph 0066).

With respect to Claim 31, MALLINKRODT teaches of the use of inorganic salts (paragraph 0055 7 0056).

With respect to Claim 32, MALLINKRODT teaches of the lysing reagent comprising hexadecyltrimethyl-ammoniumhalogenide (paragraph 0061).

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With respect to Claim 33, MALLINKRODT teaches of counting the lysed/stripped blood sample (stripped-the blood cells will be reduced in size) (Claims 12 & 14).

With respect to Claim 34, MALLINKRODT teaches of the blood cell types being monocytes and granulocytes (paragraph 0077).

With respect to Claims 35 & 36, BERNDTSSON and MALLINKRODT disclose the claimed invention except for the duplication of the mixing chamber, collection chamber, second orifice, second mixing chamber system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate these parts, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86, USPQ 70.

With respect to Claim 37, BERNDTSSON teaches of a housing with characterizing particles suspended in a liquid sample (reagent storage chamber) (column 3, lines 28-31, column 3, lines 39-48).

With respect to Claim 39, BERNDTSSON teaches of a mixing member being positioned in the mixing chamber (column 4, lines 66-67, & column 5, lines 1-17).

With respect to Claims 40 & 41, BERNDTSSON teaches of the use of a sensor for photometric measurement (column 6, lines 21-22).

With respect to Claims 42-46, BERNTSSON teaches of the hole for passage of blood cells having a diameter of 80 micrometers. It would be obvious to one of ordinary skill in the art to optimize the size of this diameter for the passage of cells.

With respect to Claims 47 & 48, MALLINKRODT teaches of the blood cell types being monocytes and granulocytes (paragraph 0077).

2. **Claims 22-48 are rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of MALLINCKRODT in EP 1182457(as cited on IDS dated 02/16/2005) and in further view of SEYMOUR in US 5393496.**

With respect to Claim 38, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31). MALLINCKRODT however teaches of the use of such a reagent (Page 11, Table 1). It would have been obvious to use the lysing reagent. BERNDTSSON and MALLINCKRODT do not teach of a breakable seal separating the reagent chamber from the mixing chamber. SEYMOUR et al. do teach of a breakable seal in a sample testing device in which the seal breaks and allows the mixture of the buffering solution and the sample to flow. It would have been obvious to combine the breakable seal of SEYMOUR with BERNDTSSON and MALLINCKRODT due to prior teaching of sampling devices in which after the specimen is obtained, the specimen collector is forced through the seal into a liquid preservative(column 2, lines 10-15).

### **Examiner's Response**

Applicant's arguments with respect to claims 22-46 have been considered but are moot in view of the new ground(s) of rejection.

Also, examiner acknowledges receipt of the foreign priority document, IDS dated 11/19/2008, and drawings replacement sheet.

### ***Conclusion***

Applicant's amendment (ADDITION OF THE NEW CLAIMS) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.F.

/Krishnan S Menon/

Primary Examiner, Art Unit 1797